Exhibit A
En-Vision America Inc.
825 4th Street West
Palmetto FL 34221
800-890-1180

optaPHONIC™

Exhibit A
AccessaMed Inc
208 West 13th Street
Vancouver WA 98660
360-696-5955

http://www.afb.org/info/programs-and-services/public-policy-center/health-and-safety/rx-label-enable-campaign/products-and-devices-to-help-you-identify-your-medications/12345

American Foundation for the blind (AFB)

Products and Devices to Help You Identify Your Medications

The U.S. Access Board has developed a best practice list of delivery methods for providing accessible prescription drug containers. Some of these methods include using electronic devices, smart phone apps, and stand-alone talking devices to identify medication.

New solutions are coming out every day. To learn about several options that are currently available, listen as Neva Fairchild, National Independent Living Associate, describes the pros and cons of several products, organizational systems, and labeling techniques.

Find a few of these and other helpful consumer products in our Product Database.

AccessaMed
Digit-Eyes
i.d. mate Quest
ScripTalk
Take-n-Slide
Talking RX Personal Talking Prescription Device
Walgreens Talking Pill Reminder
Target Prescription Bottle
Tel-Rx
Timex 2
Using a high-contrast tray

AccessaMed

Audio description of AccessaMed

Transcript

Neva: AccessaMed is a device that can be attached to prescriptions, whether they're in a bottle or a box. It is recorded by the pharmacist through speech synthesis and a special program that allows him or her to print the information – exactly as it appears on the prescription label – to the device. This eliminates the possibility of human error and sounds like this:

"George Washington, med X. Take two tablets twice a day. Rx number 21734. Fill date: July 1st, 2014. Number of refills: 6. Quantity filled 30. Round blue tablet. Expiration date: July 1st, 2015. Provider: ABC Drugs 360-555-3746. May cause drowsiness."

The recording lasts about a minute and allows the pharmacist to include information like description of the pill as well as other precautions and warnings.

Digit-Eyes

Audio description of Digit-Eyes

Transcript

Neva: Digit-Eyes is an app for your iPhone that allows you to read many things, including prescription medication labels, if your pharmacist will print a "QR" code that is readable by Digit-Eyes. A QR code is a code very similar to a barcode, only it's not shaped like a barcode and it embeds electronic information.

The app allows you to use your phone's camera to read the QR code and then the information is spoken aloud by the iPhone. The QR code information can be the information that's on the prescription label. It can also be additional information, such as warnings and precautions to be taken with certain medications.

i.d. mate Quest

Audio description of i.d. mate Quest

Transcript

Neva: The i.d. mate Quest can be used for identifying pill bottles – as well as another product the parent company [En-Vision America] makes called ScripTalk.

This one uses a barcode reader and if your medication does not come with a barcode you can add your own barcode label [included with the product]. Then you can record the information you need. Let me show you what it sounds like:

"Amoxicillin. Take three capsules daily."

Now obviously, I only recorded the bare minimum of information that was needed, but you can record as much or as little that would be helpful to you to identify your medication.

ScripTalk

Audio description of ScripTalk

Transcript

Neva: ScripTalk is a talking prescription label reading device that is available through mail order pharmacies and some brick-and-mortar pharmacies, as well as through the Veterans' Administration (VA). It's a battery-operated base station that can either hang on a wall or sit on a countertop. Each prescription is then labeled with a Radio Frequency ID Identification Label (RFID) and that RFID tag has all the printed information on the label embedded electronically. I'm going to show you how ScripTalk works.

There's a slide, or rolling switch, to turn it on in the front. "ScripTalk Station ready." That's the "get ready" boot up sound. And on the front of the unit there are three rubbery buttons. One that points down on the left, one that is an oval with a dot on it in the middle and one that points up on the right. To read a prescription label you press the one with the dot and hold the bottle above the bumped textured section of the ScripTalk.

"Patient: David Raysdrick. Medication Amoxicillin: 250 mg tablets. Instructions: Take one tablet three times daily with meals."

You can either listen to ScripTalk read the entire label straight through, or as I just did, press the down arrow and go to the next piece of information. If I missed something, I can press the up arrow and hear it again.

"Medication Amoxicillin: 250 mg tablets"

Consumer: What about privacy? What if I don't want someone to hear what's on my prescription label?

Neva: The ScripTalk has a headset jack that you can plug earphones or earbuds into. It can also connect to your computer so the information that is on the RFID tag is displayed in large print on your computer screen. Or if you have a refreshable braille display connected to your computer it can also be displayed in braille.

Consumer: Great! Should I talk to my pharmacist about this?

Neva: You should. Some pharmacies are providing this device to their customers through their mail order service, through a loan program similar to the Library of Congress [Talking Book] loan program. It's not yours to keep, but it is yours to use, and they'll provide your prescription labels with the tags once you're known as a ScripTalk user through the different pharmacies.

Consumer: I heard if I'm a veteran I might be able to get it for free.

Neva: Yes. Through the VA, a veteran who needs prescription label information read aloud can receive a ScripTalk and get their prescriptions through the VA with a ScripTalk label on them.

Take-n-Slide

Audio description of Take-n-Slide

Transcript

Neva: Take-n-Slide is a dose tracker to help you keep track of whether you have taken a particular medication and it can be used for seven day medication that you take once a day or four times a day; for example, medication that you take breakfast, lunch, dinner and at bed time.

The way it works is there is a little plastic [panel] that sticks on the side of your pill bottle and it has plastic switches that slide from left to right. You start the seven-day tracker with Monday morning. You take your Monday morning vitamin. You slide the switch to the right. Later in the day when you can't remember if you took your medication, you

can easily come back and touch the bottle and feel that the Monday switch is over to the right so you know you took your medicine.

The same thing is true of the four-time-a-day Take-n-Slide. You take your morning pills with breakfast. You take your lunch pills with lunch, and each time you slide a switch over. Then you take an afternoon nap and when you wake up from your nap you think Did I take my noon pills? You can easily go back and touch your bottle and tell either "Yes I took my noon pills" or "No I didn't."

Take-n-Slide is inexpensive and can be reused. The adhesive will allow you to use it several different times on different bottles before it needs to be replaced.

Talking RX Personal Talking Prescription Device

Audio description and example of the Talking RX

Talking RX is an audible prescription label that you can attach to a medication bottle. Or you can use the provided bottle to transfer your medication from the pharmacy's bottle into the one that fits on the Talking RX. It's a cylindrical shaped device that only has one button so there's no making a mistake. And it has a speaker so that if you are hard of hearing, you can hold the speaker closer to your ear so you can hear it. And be careful doing that because it does get quite loud. You'll have your prescription label read by the pharmacist on to Talking RX if you take it with you to the pharmacy or you can have a family member record exactly what you need. Some people would have just the basic information. [Sample: This medication is for your health. Take one pill with breakfast.] Talking RX is very flexible. It is important that the person who records the information speaks in a clear voice that you can understand.

Walgreens Talking Pill Reminder

Audio description of Walgreens Talking Pill Reminder

Transcript

Neva: Talking Pill Reminder from Walgreens is available for free when you have a prescription from a Walgreens store. It's a device that's round and adheres to your pill bottle so that it stays with the actual pill bottle.

It has two buttons: one that plays the recording of the prescription label information and one that helps the pharmacist to set the pill reminder time for you. I'm going to play a recording, or part of one, for this pill bottle that I have this device attached to.

"[Something] 100 mg capsules that is substituted for [something] 10 to 1 mg capsules. Take one capsule by mouth every six hours as needed."

This device has a small speaker that is easier to hear when held close to the ear. And it has an audible reminder to help you remember to take your medication.

Target Prescription Bottle

Audio description of Target Bottle

Transcript

Neva: Target offers pill bottles that are shaped differently so that there is more room for prescription labels; therefore the font can be printed in larger size. This also prevents the Target bottle from rolling away if it's knocked over.

Target offers differently-colored rings to attach to bottles to help a person with low vision who can perceive colors to identify their own medication more easily. For example, a husband could have blue and the wife could have red rings on all of her medicine.

Or you could use it for identifying the time of day a medication is taken. You could do yellow rings for morning breakfast medication and blue rings for night bedtime medication. These are available from Target pharmacies.

Tel-Rx

Audio description of Tel-Rx

Transcript

Neva: Tel-Rx is a talking pill bottle label that can be attached to a 13-dram [or 48 ml] bottle. It is available in other sizes as well. It's round and fits on to the cap of the bottle and has one button exposed when it's attached to the bottle for playing the recording.

"This medication is for your heart. Take one pill with breakfast."

As you can see, you can limit the amount of information for those who don't care to know the refill number, the exact name of the medication, or the number of milligrams they're taking. But obviously you can record anything you want, so those kind of details can be included if you need them.

Timex 2

Audio description of the Timex 2

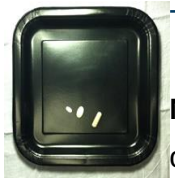
Transcript

Neva: The Timex 2 medication manger is a pill organizer and reminder system in one. It consists of a tray that holds seven [individual] trays that have snap-open compartments numbered in braille and in print.

The reminder alarm system can be detached from a tray to take with you and so can the individual trays for each day's medication. The reminder system has voice output as well as a digital display.

Using a High-Contrast tray

Audio description of Using a High-Contrast Tray



Transcript

Neva: Using a tray when you are opening pill bottles is a good idea if you are blind or visually impaired because the pill, if you drop it, will land in the tray and not roll onto the floor. It will be contained and you can find it more easily.

If the tray can contrast with the pills you are opening, it's even more helpful if you have low vision and can see the contrast of the white pill against a black tray or a purple pill against a white tray.

http://www.afb.org/section.aspx?FolderID=3&SectionID=164&TopicID=502&DocumentID=6509&rewrite=0

AMERICAN FOUNDATION FOR THE BLIND (AFB)

Information for Pharmacists: Delivery Methods for Providing Accessible Prescription Drug Container Labels

Several delivery methods are available for producing accessible prescription drug container labels in audible, braille, and large print formats.

Delivery methods include:

- **Hard copy braille and large print:** A pharmacist filling prescriptions produces hard copy braille and large print labels on request, and affixes the accessible labels to the prescription drug containers.
- **Dedicated electronic equipment:** Some equipment is designed specifically to provide accessible prescription drug container labels. Some dedicated electronic methods can be used with containers of various sizes, shapes, and materials. Examples of dedicated electronic methods include: Digital Voice or Text-to-Speech Recorder: This is a small electronic device that a pharmacist affixes to a prescription drug container. When the patient pushes a button on the device, it plays a recording of the information printed on the prescription drug container label. One device is affixed to each prescription drug container. Some devices also have a USB drive.
- **Radio Frequency Identification Device (RFID):** A pharmacist places an RFID tag on a prescription drug container. A patient who is blind or visually-impaired is equipped with a small, dedicated device that can scan and announce the text on the label. This technology may also provide prescription drug container label information in large print, and has a USB drive.
- **Smart devices and computers:** Many patients with visual impairments use their own computers and smart devices equipped with electronic braille, large print, and audio technology to access electronic text. Visually impaired computer users, particularly those who are deaf-blind, may request access to prescription drug container labels using their computers and smart devices, either via internet applications (apps) or in combination with dedicated equipment equipped with a USB drive. Methods include pharmacists placing on the prescription drug

container a QR code, RFID tag, or other small, electronic unit encoded with the prescription drug container label in electronic text, which visually impaired patients receive on smart devices or computers in electronic braille, large print, or audible format. Note that using this delivery method does not involve pharmacists embossing a braille label; rather, pharmacists use an electronic delivery method that encodes the prescription drug container label text, which can be displayed via a computer screen, speakers, or an electronic braille display.

- **About electronic label delivery methods:** Some electronic prescription drug label delivery methods may also have the capacity to include supplemental information about the prescription medications. In addition, some may have capability to translate label information into several languages.
- **The key to providing accessible prescription drug container labels is patient-centered communication among pharmacists, patients with blindness and visual impairment, patient representatives.** Because the extent of visual impairment varies from person to person, some patients may need prescription drug container labels in an audible format, while others may need braille, and still others may need large print. Additionally, it is important to keep in mind that visually impaired patients who are not computer-savvy may need hard copy braille or large print labels, or a dedicated electronic method that is easy to operate.

Excerpts From Access Board Working Group on Accessible Drug Container Labels: Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired, or Who are Elderly, July 10, 2013

For the complete Access Board report, visit: http://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels/working-group-recommendations

Exhibit D

https://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels/working-group-recommendations

United States Access Board
Advancing Full Access and Inclusion for All

Working Group Recommendations

Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind or Visually-Impaired or Who are Elderly

Access Board Working Group on Accessible Prescription Drug Container Labels

July 10, 2013

Table of Contents

Legislative Background:

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144, 126 Stat. 993). The law includes measures to promote drug safety and to improve FDA procedures for reviewing new medicines and medical devices.

A provision of the Act, **Section 904**, authorizes the Access Board to convene a stakeholder working group to develop best practices for making information on prescription drug container labels accessible to people who are blind or visually-impaired or who are elderly. (See 29 U.S.C. 792.) Under the law, representation within the working group must be divided equally between consumer and industry advocates. The Act exempts the working group from the Federal Advisory Committee Act.

The law calls for the working group to develop, no later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

According to Section 904, the best practices are not mandatory. They are not to be construed as accessibility guidelines or standards of the Access Board, nor do they confer any rights or impose any obligations on working group participants or other persons. The law makes it clear that nothing in Section 904 is to be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other federal or state law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

The law also provides that the working group may make this best practices report publicly available through the internet websites of working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities. The National Council on Disability will conduct an informational and educational campaign in cooperation with the stakeholder working group to inform the public, including people with disabilities and pharmacists, of the best practices. The Government Accountability Office will undertake a review beginning 18 months after the date of this report to assess the extent to which pharmacies are following the best practices and to what extent barriers to information on prescription drug container labels remain.

Working Group Participant Organizations

In October 2012, the Access Board formed an 18-member working group with representation from national organizations advocating for individuals who are blind, visually-impaired, and older adults, as well as industry groups representing retail, mail order, and independent community pharmacies.

The working group is comprised of representatives of the following organizations:

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)
- National Federation of the Blind (NFB)
- National Council on Patient Information and Education (NCPIE)
- Rite-Aid
- Target
- US Pharmacopeia (USP)
- Walgreens
- Wal-Mart

The working group met in person in Washington, DC, on January 10 and11, 2013, and subsequently via five teleconferences. The working group explored various alternatives, including braille, large print labels, and various auditory technologies such as "talking bottles" and radio frequency identification devices. The working group also considered whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices.

Why Are Best Practices Needed?

Persons with visual impairments who cannot read print prescription drug container labels all too often report inadvertently taking the wrong medication, the wrong amount, at the wrong time, and under the wrong instructions, thereby endangering the health and safety of themselves and family members for whom they are caregivers. Without having ready access to their prescription drug container label information, persons with visual impairments are also at risk of taking expired medications, of not being able to obtain refills in a timely manner, and of being unable to detect pharmacy errors. The majority of persons who become blind or visually-impaired do so after age 60, a time when multiple medications are often prescribed and when persons may experience physical and cognitive conditions which heighten the necessity for safe, consistent, reliable, and independent access to prescription drug container label information.

In recent years, various organizations, including US Pharmacopeia (USP), the National Association of Boards of Pharmacy, and the National Council on Patient Information and Education, have recommended the adoption of patient-centered pharmacy practices to improve patient understanding and safe, effective use of prescription medication. Inherently inclusive, patient-centered pharmacy practices promote accessibility, while a one-size-fits-all approach typically creates barriers.

In the context of this report, the term "best practice" refers to a set of working methods that the working group believes is most effective in providing access to prescription drug container label information to customers with blindness and visual impairments, including older adults.

The goal of the best practices for accessible prescription drug container labels is to offer guidance to pharmacies on how to provide accessible prescription drug container labels to patients with visual impairments to enable them to manage their medications independently and privately and have the confidence that they are taking their medications safely, securely, and as prescribed.

What Is a Prescription Drug Container Label?

A prescription drug container label is a legal document that must be prepared by the pharmacist filling the prescription. The pharmacist must ensure the accuracy of the prescription drug container label, and include on the label all elements required by applicable state law.

In 2009, USP determined optimal prescription label content and format to promote safe medication use by critically reviewing factors that promote or distract from patient understanding of prescription drug container label instructions. USP created universal prescription drug container label standards for format, appearance, content, and language (see: **U.S. Pharmacopeial Convention**). The best practices in this report build upon the USP universal patient-centered prescription drug container label standards.

Delivery Methods for Providing Accessible Prescription Drug Container Labels

A variety of delivery methods are available for producing accessible prescription drug container labels in audible, braille, and large print formats. Delivery methods include:

- Hard copy braille and large print: A pharmacist filling prescriptions produces hard copy braille and large print labels upon request, and affixes the accessible labels to the prescription drug containers.
- Dedicated electronic equipment: Some equipment is designed specifically to provide accessible prescription drug container labels. Some dedicated electronic methods can be used with containers of various sizes, shapes, and materials. Examples of dedicated electronic methods include:
    - Digital Voice or Text-to-Speech Recorder: This is a small electronic device that a pharmacist affixes to a prescription drug container. When activated by pushing a button on the device, the patient hears the information printed on the prescription drug container label. One device is affixed to each prescription drug container. Some devices also have a USB drive.
    - Radio Frequency Identification Device (RFID): A pharmacist places an RFID tag on a prescription drug container. A patient who is blind or visually-impaired is equipped with a small, dedicated device that, when a container with an RFI Tag is placed over the device, audibly announces the text on the prescription drug container label. This technology may also provide prescription drug container label information in large print, and has a USB drive.
    - Smart devices and computers: Many patients with visual impairments use their own computers and smart devices equipped with electronic braille, large print, and audio technology to access electronic text. Visually impaired computer users, particularly those who are deaf-blind, may request access to prescription drug container labels using their computers and smart devices, either via internet applications (apps) or in combination with dedicated equipment equipped with a USB drive. Methods include pharmacists placing on the prescription drug container a QR code, RFI tag, or other small, electronic unit encoded with the prescription drug container label in electronic text, which visually impaired patients receive on smart devices or computers in electronic braille, large print, or audible format. Note that using this delivery method does not involve pharmacists embossing a braille label; rather, pharmacists use an electronic delivery method that encodes the prescription drug container label text, which can be displayed via a computer screen, speakers, or an electronic braille display.

Some electronic prescription drug container label delivery methods may also have the capacity to include supplemental information about the prescription medications. In addition, some may have capability to translate prescription drug container label information into several languages.

The key to providing accessible prescription drug container labels is patient-centered communication between pharmacists and patients with blindness and visual impairment and patient representatives. Because the extent of visual impairment varies from person to person, some patients may need prescription drug container labels in an audible format, while others may need braille, and still others may need large print. Additionally, it is important to keep in mind that visually impaired patients who are not computer savvy may need hard copy braille or large print labels, or a dedicated electronic method that is easy to operate.

Best Practices to Use for All Formats

The following best practices promote access to prescription drug container label information in all formats, including audible, braille, and large print labels.

- One of the best things pharmacists can do is to encourage patients and patient representatives to communicate their needs to pharmacists:
  - Advertise a local or, when possible, a toll-free telephone number to promote communication between patients and pharmacists;
  - If pharmacy websites and applications (apps) are made available to patients, ensure website and app accessibility; and
  - When a pharmacist observes a patient or patient representative having reading difficulty, offer education and counseling in a setting that maintains patient privacy.
- Follow universal patient-centered prescription drug container label standards.
- Make available options for accessible prescription drug container labels in audible, braille, and large print formats via methods using, for example, hard copy, dedicated devices, and computers or smart devices.
- Explain to the patient the available accessible prescription drug container label format options, and provide the prescription drug container label in the format option selected by the patient.
- Ensure that duplicate accessible labels preserve the integrity of the print prescription drug container label.
- Subject accessible prescription drug container labels to the same quality control processes used for print labels to ensure accuracy and patient safety.
- Maintain patient privacy in accordance with the Health Insurance Portability and Accountability Act (HIPAA) rules when preparing accessible prescription drug container labels, e.g., record audible labels in a location where patient information cannot be overheard by unauthorized persons.
- In advance, make arrangements to provide accessible prescription drug container labels. For example, maintain a sufficient inventory of supplies necessary to support timely provision of prescription drug container labels in accessible label formats.
- Provide prescription medication with an accessible prescription drug label within the time frame the same prescription would be provided to patients without visual impairments.
- Do not impose a surcharge or extra fee to an individual to cover the cost of providing an accessible drug container label and equipment dedicated for prescription drug container label access.
- Ensure the durability of accessible label format options until the expiration date specified on the prescription drug container label.
- Select a container that best supports the type of accessible label provided.
- For all accessible label formats, including audible formats, ensure that all required information contained on the print prescription drug container label is provided on the accessible label in the same sequence as the print label.
- Include in accessible prescription drug container labels the information on warning labels added to the container at the pharmacist's discretion.

Format-Specific Best Practices

In addition to the best practices listed above, please note the following format-specific best practices.

Audible Prescription Drug Labels

For dedicated equipment, select devices that provide independent, easy to use, start/stop operation, with volume control, and ear bud access for privacy.

If using a voice recorder:

- speak in a clear voice;
- record information in a setting that minimizes background noise and maintains patient privacy.

Offer to show the patient how to operate the audible prescription drug container label.

Braille Prescription Drug Container Labels

Electronic delivery method: Acquire an electronic delivery method using RFI tags, QR codes, or other processes to provide electronic text of the prescription drug container label upon request. Consumers with electronic braille equipment may then access electronic text in braille format.

Note that, as required, the working group considered significant challenges that pharmacies may face in producing drug labels in accessible formats, such as hard copy braille. The working group recognizes that mail order and online pharmacies, because of their centralized structure, large volume, and mail delivery process, may be better equipped than local stores to provide hard copy braille prescription drug container labels. Many mail order and online pharmacies have established a unit with the necessary computer software and braille embossers to produce hard copy braille labels and a protocol to develop pharmacists' proficiency in printing accurate braille labels.

- If a local pharmacy store has a high demand for hard copy braille prescription drug container labels, acquire on-site braille embosser capacity and proficiency.
- If a local pharmacy store receives infrequent or occasional requests for hard copy braille prescription drug container labels, partner with a pharmacy that has braille prescription drug container labeling capacity to provide a hard copy braille prescription drug container label.

When embossing hard copy braille prescription drug container labels:

- Use contracted (Grade 2) braille.
- Emboss braille labels on transparent material in order to preserve the legibility of print container labels. Affix braille label to the prescription drug container with strong adhesive.
- Do not fold braille labels.

Printing Large Print Labels (hard copy):

- Print label in 18-point bold font.
- Use non-glossy paper or other material that is durable and a size that is easy to manipulate.
- Use print with highest possible contrast between text and background color (ideally black text on a white or pale yellow background). If printing on both sides, use material that does not allow print bleed-through from one side to the other.
- Use sentence case, with the initial capital letter followed by lower-case characters.
- Use non-condensed, san-serif font, such as Arial.
- Provide 1.5 line spacing.
- Use horizontal text only.
- Securely affix the large print label to the prescription drug container.
- When covering a large print label with protective tape, use non-glossy, transparent tape.

Resources

USP Patient-Centered Prescription Label Standards

UMS White Paper, The National Council for Prescription Drug Programs Work Group (WG), 2013

Working Group Participant Organizations

- AARP
- American Council of the Blind (ACB)
- American Foundation for the Blind (AFB)
- Blinded Veterans Association (BVA)
- Council of Citizens with Low Vision International (CCLVI)
- Express Scripts
- Metropolitan Washington Association of the Deaf Blind (MWADB)
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council on Aging (NCOA)
- National Council on Independent Living (NCIL)

- National Council on Patient Information and Education (NCPIE)
- National Federation of the Blind (NFB)
- Rite-Aid
- Target
- US Pharmacopeia (USP)
- Walgreens
- Wal-Mart

American Pharmacists Association Nondiscrimination: New HHS regulation affects pharmacies

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June 13, 2016

Final rule is effective July 18, with additional deadlines later this year

A final rule issued by the federal government may allow civil lawsuits against pharmacies that deny language assistance services to patients with limited English proficiency or refuse to treat patients in a manner consistent with their gender identity. The U.S. Department of Health & Human Services (HHS) rule is aimed at advancing health equity and reducing disparities in health care.

The rule, which implements Section 1557 of the Affordable Care Act (ACA), requires health care entities receiving federal financial assistance—such as those that accept Medicaid and Medicare—to engage in certain practices to prevent discrimination on the basis of age, race, color, nationality, or gender, including gender identity. It also applies to programs that HHS itself administers and health plans sold in the marketplace.

The rule's effective date is July 18, 2016, and includes additional deadlines in October and December.

The heart of the rule

Section 1557 has the distinction of being the first federal rule to prohibit discrimination on the basis of gender identity in federally funded health programs. Previous civil rights laws enforced by HHS's Office for Civil Rights (OCR) broadly barred discrimination only if based on race, color, national origin, disability, or age. Gender identity discrimination includes refusal to dispense transition-related medications.

HHS clarifies that, in addition to gender identity, discrimination based on pregnancy and sex stereotyping qualifies as sex discrimination.

At the heart of the rule are requirements that pharmacies take reasonable steps to provide meaningful access to individuals with limited English proficiency or a disability, particularly people who are blind or deaf. The rule includes a requirement that pharmacies display posters informing patients that the pharmacy will offer language assistance to patients who need it. HHS will make the notices translated into several languages available online to ease costs and facilitate compliance.

Individuals who pursue civil actions based on Section 1557 can now use the rule's requirements to help prove that a health care entity discriminated against them, which could expose pharmacies to liability for actions that previously may not have been found discriminatory. The burden is on the plaintiff, however, to prove that services were denied due to discrimination—not simply that the pharmacy failed to provide them.

Patients also have the option to submit reports of civil rights violations to the Office for Civil Rights (OCR) at www.hhs.gov/ocr.

Next steps for pharmacies

The rule suggests—but does not require—that pharmacies develop language access plans to improve compliance and increase access to language services. It's not safe harbor from the rule, but having such a plan will weigh favorably in the event of a discrimination complaint or an investigation into whether the entity has taken reasonable steps to provide meaningful access.

https://www.pharmacist.com/nondiscrimination-new-hhs-regulation-affects-pharmacies

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Federal nondiscrimination regulation imposes key requirements on pharmacies

Share This Page

July 01, 2016

Most of the provisions relevant to pharmacies take effect July 18

On May 18, the U.S. Department of Health & Human Services (HHS) and its Office of Civil Rights released the Nondiscrimination in Health Programs and Activities Final Rule. According to HHS, under the Rule, individuals are protected from discrimination in health coverage and care on the basis of race, color, national origin, age, disability, and sex, including discrimination based on pregnancy, gender identity, and sex stereotyping.

In addition to implementing Section 1557 of the Affordable Care Act's prohibition on sex discrimination, the Final Rule also enhances language assistance for people with limited English proficiency and helps to ensure effective communication for individuals with disabilities. This regulation is applicable to health care entities and providers receiving federal funds from HHS, such as health insurers, hospitals, physicians, and pharmacies.

Most of the provisions relevant to pharmacies take effect on **July 18, 2016**.

Key requirements for covered entities (i.e., pharmacies):

The compliance date of the below requirements is July 18, 2016, unless otherwise noted.

1. Designation of responsible employee (only if the covered entity has 15 or more employees)

- **Tip:** Pharmacies that have a designated employee to satisfy standards under Section 504 or Title IX may use that individual to comply with Section 1557.

2. Adoption of grievance procedures (only if the covered entity has 15 or more employees)

- **Tip:** Pharmacies that have a grievance procedure to satisfy standards under Section 504 may use that procedure to address disability claims under Section 1557 and all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin sex, and age discrimination.

- **Useful resource:** Example of a Section 504 grievance procedure that incorporates due process standards (http://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/section-504-grievance-procedure/index.html)

3. File assurance of compliance form when applying for federal funding

- **Useful resource:** Assurance of compliance form (HHS 690 Form): http://www.hhs.gov/sites/default/files/hhs-690.pdf

4. Training (encouraged, not required)

- **Useful resource:** To facilitate training that covered entities choose to provide, OCR will make available a training curriculum, and will engage in outreach and technical assistance to promote understanding of and compliance with the final rule (as of May 25, this resource has not been made available).

5. Notices of nondiscrimination and taglines (pharmacies must comply within 90 days of the rule's July 18 effective date):

- Covered entities must give notice regarding nondiscrimination and available services in conspicuous physical locations (i.e., in store), online (if applicable) and in substantial publications, including small-sized publications.

- 15 taglines must be included in notices in physical locations, online, and substantial publications. (Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.)

- 2 taglines must be included in notices in small-sized substantial publications

- **Tip:** May combine the notice's content with the content of other notices

- **Useful Resource:** Translated materials for covered entities (http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html)

6. Take reasonable steps to provide meaningful access, free of charge and in a timely manner, for individuals with limited English proficiency (LEP)

- Covered entity cannot: require a LEP individual to provide his/her own interpreter; rely on an adult accompanying an individual with LEP to interpret or facilitate communication (exceptions for emergencies and specific requests); rely on staff other than qualified bilingual/multilingual staff to communicate directly with LEP individuals

- **Tip:** Although individuals with LEP are not required to accept language assistance services, covered entities should document when such services are offered and the patients refuses them.

- **Resource:** HHS Language Access Plan (2013) http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf (referenced in the Final Rule)

- **Note:** Language access plan is not required, but APhA **strongly encourages** covered entities to develop a language access plan to limit gaps in access and help prevent discrimination claims

7. Take reasonable steps to provide meaningful access, free of charge and in a timely manner to provide effective communication for individuals with disability.

8. Must make accessible electronic and information technology programs or activities to individuals with disabilities unless there are undue financial and administrative burdens or a fundamental alteration in the nature of the health program or activity.

9. Must make reasonable modifications when necessary to avoid discrimination on the basis of disability.

Here is more detailed information about the Final Rule and requirements for pharmacies.

Nothing in this document should be perceived as legal advice; available for informational purposes only.

Jenna Ventresca, JD, APhA Associate Director of Health Policy

https://www.pharmacist.com/federal-nondiscrimination-regulation-imposes-key-requirements-pharmacies

Accessible Prescription Laws Time Line

1973: Rehabilitation Act banned discrimination on the basis of disability by recipients of federal funds

May 4, 1977: Section 504 regulations were issued. It is these regulations which form the basis of the ADA

July 26, 1990: ADA signed into law

1996: En-Vision America founded. Invention of ScripTalk
1996: Talk RX prototype released
1999: ALOUD prototype released

2001: ScripTalk pilot at Rush Presbyterian Medical Centre in Chicago and Hines VA

December 8, 2003: George W. Bush signed the Medicare Prescription Drug Improvement and Modernization Act of 2003. This Act required the DHHS to study how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible for the blind and low vision. The DHHS formulated study questions and the AFB responded with information about the blind population, access to prescription information, and existing and emerging technologies. They made some recommendations that the National Eye Health Education Program conduct an education program and publish materials letting patients and pharmacies know about assistive technologies and modalities for accessing prescription drug information. The NEHEP director, Neyal Ammary-Risch says that they never performed with work due to budget cuts and because the AFB published some really good information to their website and worked with the Pharmaceutical industry to create standards regarding labels (this occurred in 2012).

September 8, 2004: Veterans Administration Announced the Standardization of Audible Prescription Reading Devices with ScripTalk as the standard.

January 16, 2009: Indiana HB1627 introduced to require Braille or recorded audio device for prescription labels. Passed Senate 4/15/09. No end result.

May 2009: Massachusetts Senate Bill 445 introduced An Act Relative to Coverage for Prescription Drug Voice Synthesizers. No end Result.

Feb 2010: Indiana HB1240 Various Insurance Matters included language for prescription drug labeling. No end result.

2010: ADA Amendments provided detailed and clarified instructions on how public accommodations—specifically citing pharmacies—must provide auxiliary aids and services to blind or low-vision customers in order to provide effective communication.

The new language goes on specifically to list large-print materials, Braille materials, and accessible electronic and information technology as recommended solutions.

January 11, 2012: Indiana HOUSE BILL No. 1301 Introduced. This bill would provide tax credit for pharmacies piloting incorporation of assistive technologies into packaging of prescriptions for blind or visually impaired. Currently in Ways and Means Committee (as of 1/27/14)

February 2012: H.R 4087 introduced by Congressman Edward J. Markey (D-Mass). House of Representatives passed

June 26, 2012: Senate passes S3187

July 9, 2012: President Obama signs into law the Food and Drug Administration Safety and Innovation Act

July 10, 2013: United States Access Board releases "Best Practices"

January 22, 2013: Massachusetts H.900 and S.472 Introduced regarding An Act relative to prescription drug voice synthesizers. (S.472 3/25/2014 Accompanied a study order, see S2064) (H. 900 4/15/2015 Accompanied a study order, see H.4039)

July 2013: Introduction of AccessaMed at NFB conference

Januray 2015: Senatory Markey requests feedback from major pharmacies on their progress of implementing "Best Practices"

May 13, 2016: Affordable Care Act Section 1557 Nondiscrimination in Health Programs and Activities final rule issued. § 92.202 Effective communication for individuals with disabilities. A *covered entity* must provide auxiliary aids and services to individuals with disabilities free of charge and in a timely manner when necessary to ensure an equal opportunity to participate and benefit from the entity's health programs or activities. This is holding all covered entities to the higher ADA Title II standards.

December 9, 2016 Government Accountability Office reports: "Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who are Blind or Visually Impaired" http://www.gao.gov/products/GAO-17-115

February 2017 Nevada Senate Bill 131 proposed
http://www.leg.state.nv.us/Session/77th2013/Bills/SB/SB131_EN.pdf

PRESCRIPTION READER

LEGAL REQUIREMENTS FOR PROVIDING AS A REASONABLE ACCOMMODATION UNDER AMERICANS WITH DISABILITIES ACT, TITLE III SECTION 504 OF THE REHABILITATION ACT SECTION 1557 AFFORDABLE CARE ACT

ADA TITLE III: REQUIRES PROVISION OF AUXILIARY AIDS AND SERVICES

> **§36.303(a) Auxiliary aids and services: General**. A public accommodation shall take those steps that may be necessary to ensure that no individual with a disability is excluded, denied services, segregated or otherwise treated differently than other individuals because of the absence of auxiliary aids and services, unless the public accommodation can demonstrate that taking those steps would fundamentally alter the nature of the services....or would result in an undue burden, i.e., significant difficulty or expense.

ADA TITLE III – NO SURCHARGE FOR AUXILIARY AIDS AND SERVICES

> **§36.301(C) Charges:** A public accommodation may not impose a surcharge on a particular individual with a disability or any group of individuals with disabilities to cover the costs of measures, such as the provision of auxiliary aids, barrier removal...and reasonable modifications in policies, practices, or procedures, that are required to provide that individual or group with the nondiscriminatory treatment required by the Act or this part.

SECTION 504 OF THE REHABILITATION ACT: NON-DISCRIMINATION

> **§84.52 Health, welfare, and other social services.**
>
> **(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:**
>
> **(1) Deny a qualified handicapped person these benefits or services;**
>
> **(2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered non-handicapped persons;**

(3) Provide a qualified handicapped person with benefits or services that are not as effective (as defined in §84.4(b)) as the benefits or services provided to others;

SECTION 504 – REQUIRES PROVISION OF AUXILIARY AIDS AND SERVICES

§84.52(d) *Auxiliary aids.* (1) A recipient to which this subpart applies that employs fifteen or more persons shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(2) The Director may require recipients with fewer than fifteen employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services.

(3) For the purpose of this paragraph, auxiliary aids may include brailled and taped material, interpreters, and other aids for persons with impaired hearing or vision.

ACA – FROM AMERICAN PHARMACISTS ASSOCIATION

“At the heart of the rule are requirements that pharmacies take reasonable steps to provide meaningful access to individuals with limited English proficiency or a disability, particularly people who are blind or deaf. The rule includes a requirement that pharmacies display posters informing patients that the pharmacy will offer language assistance to patients who need it.”

“Individuals who pursue civil actions based on Section 1557 can now use the rule’s requirements to help prove that a health care entity discriminated against them, which could expose pharmacies to liability for actions that previously may not have been found discriminatory.”June 13, 2016 American Pharmacists Association.

http://www.afb.org/info/blindness-statistics/state-specific-statistical-information/nevada/235

AFB American Foundation for the Blind ®

Nevada

Updated January 2017

2015 Prevalence Rates of Visual Loss

Total	108,054
Gender	
Male	53,371
Female	54,683
Age	
Under 5	3,262
5-17	10,694
18-34	16,168
35-64	45,926
65-74	14,087
75 and older	17,917

2014 Prevalence Rates of Visual Loss

Total	85,941
Gender	
Male	39,482
Female	46,459
Age	
Under 5	1,879
5-17	8,374
18-34	14,125
35-64	33,293
65-74	13,370

Exhibit H